

**REMARKS****I. APPLICANTS' INVENTION**

The present invention relates to an endoprosthesis assembly including an implantable prosthesis (e.g., a diametrically expandable stent device, with or without a graft covering) provided with a delicate constraining sheath located coaxially around the endoprosthesis. The assembly is further provided with means for disruption of the constraining sheath (e.g., a catheter balloon) to initiate deployment of the endoprosthesis. The endoprosthesis may be a balloon expandable endoprosthesis but more preferably is a self-expanding prosthesis. The constraining sheath is delicate, meaning that it is capable of retaining the endoprosthesis in a compressed state (i.e., at its small, compacted diameter) suitable for insertion into a body cavity, for a limited period of time. If left indefinitely around the endoprosthesis, such a delicate constraining sheath will yield to the diametrically outwardly directed force applied by a constrained self-expandable endoprosthesis. Accordingly, the delicate constraining sheath is enclosed within a packaging sheath of strength adequate to contain the endoprosthesis indefinitely, and is removed after the endoprosthesis is removed from its shipping package and prior to insertion of the endoprosthesis into a body cavity. The advantage of the use of such a delicate constraining sheath is its thin wall, which offers minimal interference when the constrained endoprosthesis is inserted into a body cavity such as the vasculature.

The constraining sheath may optionally be implantable, and as such, following deployment of the endoprosthesis, remains captive between the deployed endoprosthesis and the luminal surface of the body cavity at the site of implantation. Alternatively, the delicate constraining sheath may be attached to the delivery catheter and withdrawn with that catheter following deployment of the endoprosthesis. The constraining sheath is preferably made of ePTFE.

The constraining sheath and endoprosthesis are preferably mounted together as an assembly on an angioplasty balloon for delivery. Deployment of the endoprosthesis entails inflating the angioplasty balloon to a pressure sufficient to disrupt or break the constraining sheath in a prescribed fashion, thereby allowing a self-expanding endoprosthesis to spontaneously deploy.

**II. CLAIM REJECTIONS**

Claims 1, 11, 21, 31 and 41-42 stand rejected under 35 USC 103(a) as unpatentable over Thornton et al., US 6,015,431. The Examiner states that claims 2-10, 12-20, 22-30 and 32-40 are objected to as being dependent upon a rejected base claim but allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Accordingly, claim 1 is amended herein by the addition of all of the limitations of claim 2; consequently claim 2 is now canceled. Claims 11, 21 and 31 are now patentable as they depend from now-amended and patentable claim 1. Claims 12, 22 and 32 are now canceled as they contain the same limitations as claim 2, also canceled.

Finally, rejected claims 41-42 are also canceled.

### CONCLUSION

The applicants believe that their claims as amended are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully Submitted,



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